MEDICAL EVALUATORS
OF TEXAS ASO, L.L.C.
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DATE OF REVIEW: December 16, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Denial of coverage for bilateral cervical transforaminal epidural steroid injection

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
This case was reviewed by a physician who holds a board certification in Anesthesiology with sub-certification in Pain Medicine. The reviewer is currently licensed and practicing in the state of Texas.

REVIEW OUTCOME
Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

EMPLOYEE CLINICAL HISTORY [SUMMARY]:
This is a female who sustained a work-related injury on xx/xx/xx while she was employed. She was rear-ended by a pick-up truck while she was waiting at a stop sign. She reported injury to her neck and lower back with radiating pain in both arms and right leg. The claimant has been treated previously with physical therapy, medications, chiropractic treatment, cervical ESIs and lumbar ESIs. The claimant previously received a C5-6 transforaminal ESI on 10/31/2014 with 60% relief of pain. The claimant had MRI of the cervical spine that showed disc protrusions/herniations at C5-6 measuring 5.5 mm and C6-7 measuring 3.5 mm without spinal stenosis.

The progress note dated 10/23/2015 documented the examinee to have cervical pain radiating to upper back/shoulders. The pain level was noted to be 6/10. Current medication included Norco. On physical examination, cervical and lumbar spine ROM was decreased, there was no atrophy and sensation was intact throughout. Neurologic exam was normal. The claimant was diagnosed with chronic pain syndrome, sprain of unspecified parts of thorax, sprain of ligaments of cervical spine, and sprain of unspecified shoulder joint. The doctor recommended cervical injection at C4-C5 and C5-C6.

Prior UR dated 11/05/2015 denied the request for C4-C5 and C5-C6 bilateral cervical transforaminal epidural steroid injection based on the risk far outweighs any potential

benefit. It is noted that the current medication protocol has been changed. Additionally, there is no evidence to suggest a verifiable radiculopathy either on physical examination or corroborated with electrodiagnostic studies. Therefore, based on the clinical information presented for review, with the understanding that there is a disc lesion noted at C5-C6 and C6-C7, when considering the specific parameters identified in the ODG tempered by the lack of any objectification of a verifiable radiculopathy, this is not warranted.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

After careful review of the medical records, the previous adverse determination on the request for cervical transforaminal epidural injections is upheld**.** As per ODG, the criteria for cervical ESI requires "radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing." In this case, the claimant has subjective complaints of radicular pain in the upper arms; however, there is no documentation of physical findings suggestive of radiculopathy. Based on the progress notes, the physical exam showed sensation in the upper extremities was intact. There was no documentation of motor testing or reflexes in the upper extremities.

Therefore, based on the ODG criteria as well as the clinical documentation stated above, the request is not medically necessary.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

ODG Chapter - Neck and Upper Back (Acute & Chronic) – Online Version accessed 12/14/2015

Epidural steroid injections (ESIs)

Not recommended based on recent evidence, given the serious risks of this procedure in the cervical region, and the lack of quality evidence for sustained benefit. These had been recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy), with specific criteria for use below. In a previous Cochrane review, there was only one study that reported improvement in pain and function at four weeks and also one year in individuals with radiating chronic neck pain. (Peloso-Cochrane, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of cervical nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A previous retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with

symptomatic cervical radiculopathy from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). (Lin, 2006) There have been case reports of cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. (Beckman, 2006) (Ludwig, 2005) Quadriparesis with a cervical ESI at C6-7 has also been noted (Bose, 2005) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after cervical ESI (1970-1999). (Fitzgibbon, 2004) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. (Ma, 2005) The American Academy of Neurology concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) In other studies, there was evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to decrease the rate of open surgery. (Haldeman, 2008) (Benyamin, 2009) Some have said epidural steroid injections should be reserved for those who may otherwise undergo open surgery for nerve root compromise. (Bigos, 1999) There is limited evidence of effectiveness of epidural injection of methyl prednisolone and lidocaine for chronic MND with radicular findings. (Peloso-Cochrane, 2006) The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (FDA, 2014)
Recent evidence: ESIs should not be recommended in the cervical region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded. Injecting a particulate steroid in the cervical region, especially using the transforaminal approach, increases the risk for sometimes serious and irreversible neurological adverse events, including stroke, paraplegia, spinal cord infarction, and even death. The FDA has never approved an injectable corticosteroid product administered via epidural injection, so this use, although common, is considered off-label. Injections into the cervical region, as opposed to the lumbar area, are relatively risky, and the risk for accidental injury in the arterial system is greater in this location. (FDA, 2015) An AMA review suggested that ESIs are not recommended higher than the C6-7 level; no cervical interlaminar ESI should be undertaken at any segmental level without preprocedural review; & particulate steroids should not be used in therapeutic cervical transforaminal injections. (Benzon, 2015) According to the American Academy of Neurology (AAN), ESIs do not improve function, lessen need for surgery, or provide long-term pain relief, and the routine use of ESIs is not recommended. They further said that there is in particular a paucity of evidence for the use of ESIs to treat radicular cervical pain. (AAN, 2015) In this comparative-effectiveness study, no significant differences were found between ESI and conservative treatments. (Cohen, 2014) See the Low Back Chapter, where ESIs are recommended as a possible option for short-term treatment of radicular pain in conjunction with active rehab efforts, but they are not recommended for spinal stenosis or for nonspecific low back pain.

While not recommended, cervical ESIs may be supported using Appendix D, Documenting Exceptions to the Guidelines, in which case:

Criteria for the use of Epidural steroid injections, therapeutic:

Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

(1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing.

(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).

(3) Injections should be performed using fluoroscopy (live x-ray) for guidance

(4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.

(5) No more than two nerve root levels should be injected using transforaminal blocks.

(6) No more than one interlaminar level should be injected at one session.

(7) In the therapeutic phase, repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year.

(8) Repeat injections should be based on continued objective documented pain and function response.

(9) Current research does not support a “series-of-three” injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.

(10) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.

(11) Cervical and lumbar epidural steroid injection should not be performed on the same day;

(12) Additional criteria based on evidence of risk:

- (a) ESIs are not recommended higher than the C6-7 level;
- (b) Cervical interlaminar ESI is not recommended; &
- (c) Particulate steroids should not be used. (Benzon, 2015)

Criteria for the use of Epidural steroid injections, diagnostic:

To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:

(1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies;

(2) To help to determine pain generators when there is evidence of multi-level nerve root compression;

(3) To help to determine pain generators when clinical findings are suggestive of radiculopathy (e.g. dermatomal distribution), and imaging studies have suggestive cause for symptoms but are inconclusive;

(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

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NOTICE ABOUT CERTAIN INFORMATION LAWS AND PRACTICES With few exceptions, you are entitled to be informed about the information that the Texas Department of Insurance (TDI) collects about you. Under sections 552.021 and 552.023 of the Texas Government Code, you have a right to review or receive copies of information about yourself, including private information. However, TDI may withhold information for reasons other than to protect your right to privacy. Under section 559.004 of the Texas Government Code, you are entitled to request that TDI correct information that TDI has about you that is incorrect. For more information about the procedure and costs for obtaining information from TDI or about the procedure for correcting information kept by TDI, please contact the Agency Counsel Section of TDI's General Counsel Division at (512) 676-6551 or visit the Corrections Procedure section of TDI's website at www.tdi.texas.gov.